UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

BARBARA PORTER, as Trustee for the Heirs and Next of Kin of Gaylene Johnson, deceased, Plaintiff, vs. XANODYNE PHARMACEUTICALS INC., AAIPHARMA INC., TEVA USA, WEST-WARD PHARMACEUTICAL CORP., WATSON PHARMACEUTICAL, and DOES ONE through SIXTY, inclusive, Defendants.	CASE NUMBER 07-3344 JMR/FLN **COMPLAINT AND DEMAND FOR JURY TRIAL**

SCANNED
JUL 16 2007
U.S. DISTRICT COURT MPLS

I. PARTIES AND JURISDICTION

1. Plaintiff, Barbara Porter, at all times relevant herein, the court appointed trustee for the heirs of Gaylene Johnson, decedent. A copy of this appointment is attached to the Complaint as Exhibit A. Plaintiff's Decedent, Gaylene Johnson, was prescribed propoxyphene and died from its ingestion on July 18, 2004.

2. Defendants Xanodyne Pharmaceuticals Inc., aaiPharma Inc., Teva USA, West-Ward Pharmaceutical Corp., Watson Pharmaceutical, and Does One through Sixty will hereafter be referred to as "Defendants".

3. Defendants did business in Minnesota on and before July 18, 2004 through the distribution and sale of Propoxyphene, manufactured by Defendants.

4. The defendants caused tortious injury in the state of Minnesota and West Virginia through the sale and distribution of a defective product, Propoxyphene. The product caused injuries leading to the death of Gaylene Johnson on July 18, 2004.

WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

II.

A. PROPOXYPHENE Manufactured and Sold by DEFENDANTS

Paragraphs 1-4 are herein incorporated by reference:

5. Doctors, including Gaylene Johnson's doctors, and patients, including Gaylene Johnson, relied upon Defendants' representations that the Propoxyphene product was safe and effective to use.

B. PROPOXYPHENE

Paragraphs 1-5 are herein incorporated by reference:

6. Propoxyphene was specifically designed, manufactured, and sold by Defendants to treat pain.

7. During all times herein, Defendants represented that Propoxyphene was safe for the treatment of pain. Propoxyphene is a prescription painkiller.

C. PROPOXYPHENE complications

Paragraphs 1-7 are herein incorporated by reference:

8. Propoxyphene is an analgesic (pain killer) used for relief of most kinds of pain, including post-operative pain. It was originally developed by Eli Lilly and has been on the market since 1957. Eli Lilly no longer manufactures propoxyphene, as it sold the rights to these drugs to aaiPharma several years ago. Today, propoxyphene is sold as a generic drug.

9. Over the past 47 years, propoxyphene has been one of the deadliest drugs on the market, being associated with well over 10,000 confirmed deaths in the United States alone. From 1981 to 1999, the Drug Abuse Warning Network (DAWN) reported 2,110 propoxyphene-related accidental deaths. It is almost certain that the actual number of accidental deaths due to propoxyphene is significantly higher than the number reported.

10. Many studies have shown the relative ineffectiveness of propoxyphene as a painkiller. A recent comprehensive review of randomized clinical trials found that for most kinds of pain (e.g., post-operative pain), ibuprofen is more effective than propoxyphene/acetaminophen (the latter, the ingredient in Tylenol).

11. Upon metabolism, the majority of propoxyphene is converted into norpropoxyphene, a cardiotoxic metabolite that is more toxic and has a longer half-life than its parent compound.

12. Propoxyphene can cause severe cardiovascular effects with overdose or even when used as directed, including abnormal cardiac rhythm, interruption of cardiac conduction, slowed heart beat, absence of contractions, diminished myocardial contractility, and hypotension.

13. There is much evidence that propoxyphene can produce physical addiction, as manifested by withdrawal symptoms, strong psychological dependence, and tolerance. Addiction can occur at less than the maximum daily recommended dose of 390 mg.

14. Propoxyphene is a drug with potential for abuse. When 6-10 pills are orally administered, the drug can induce patients to experience effects similar to those from marijuana, heroin, morphine, and cocaine. In 2002, 1680 out of 4676 or 36% of people with an emergency room visit related to propoxyphene indicated that either psychic effects or dependence on propoxyphene were the reason for the emergency room visit.

15. Phased withdrawal of products containing propoxyphene was announced by the British government in 2005, with the government citing unacceptable risks of toxicity in overdose and poorly established efficacy of this product, with all patient groups reporting negative risk-benefit ratio.

16. Gaylene Johnson was prescribed propoxyphene to help treat pain in her back due to severe scoliosis, as well as leg pain and post-operative surgery pain.

17. Prior to July 18, 2004 Gaylene Johnson ingested propoxyphene and on July 18th, 2004 Gaylene Johnson died from propoxyphene intoxication.

WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

III. CAUSES OF ACTION

A. Negligence

Paragraphs 1-17 are herein incorporated by reference:

18. The defendants owed Gaylene Johnson a duty of reasonable care with respect to their propoxyphene products.

19. The defendants breached this duty by:

a. failing to use reasonable care with respect to patient safety in designing, testing, and manufacturing propoxyphene

b. failing to adequately warn Gaylene Johnson, either directly or through physician intermediaries, of the scope and nature of the risk of complications associated with propoxyphene

c. promoting the benefits of propoxyphene while deliberately concealing the level of risk associated with it.

d. violating federal regulations applicable to prescription drugs such as propoxyphene, such as those covering labeling and post-marketing reporting of adverse events.

e. negligent tracking, follow up and reporting of adverse events of propoxyphene

f. failing to provide all safety information concerning the effectiveness and side effects of propoxyphene

B. Strict Liability

Paragraphs 1-19 are herein incorporated by reference:

20. The defendants placed propoxyphene into the stream of commerce as an integral part of their business in an effort to treat Gaylene Johnson's pain.

21. The propoxyphene used in an effort to treat Gaylene Johnson was defective in the sense that it was not reasonably safe for its intended use and Defendants were aware of it.

22. The propoxyphene used in an effort to treat Gaylene Johnson was defective at the time the defendants put it into the stream of commerce, and it reached Gaylene Johnson in substantially the same condition it was in when it was placed into the stream of commerce.

F. Implied Warranty

Paragraphs 1-22 are herein incorporated by reference:

23. Propoxyphene carried a warranty of merchantability, fitness for its intended purpose, and reasonable safety implied by law.

24. The defendants breached this warranty because propoxyphene was not reasonably safe for its intended purpose and was not of merchantable quality.

25. Gaylene Johnson and her physicians relied on this implied warranty.

G. Deceptive Trade Practice

Paragraphs 1-25 are herein incorporated by reference:

26. Defendants deceptively and misleadingly concealed material defects with propoxyphene and adverse event data from the FDA, physicians and consumers in order to deceive doctors and patients like Gaylene Johnson into believing there were significantly fewer adverse events than there really were.

IV. FRAUD BY CONCEALMENT

Paragraphs 1-26 are herein incorporated by reference:

27. At all times mentioned herein, Defendants had the duty and obligation to disclose to Plaintiff, and to her physicians, the true facts concerning the aforesaid product; that is, that said product was dangerous, defective, and likely to cause serious injuries to users, including injuries as herein occurred, and how unnecessary it was to use said product for the purposes indicated. Defendants made the affirmative representations as set forth above to Plaintiff, her physicians and the general public prior to the date that propoxyphene was prescribed to Plaintiff, while concealing the following material facts.

28. At all times mentioned herein, Defendants had the duty and obligation to disclose to Plaintiff and to her physicians the true facts concerning the aforesaid product; that is, that use could cause injuries including but not limited to poisoning and death.

29. At all times herein mentioned, Defendants intentionally, willfully, and maliciously concealed or suppressed the facts set forth above from Plaintiff's physicians and therefore from Plaintiff, with the intent to defraud as herein alleged.

30. At all times herein mentioned, neither Plaintiff nor her physicians were aware of the facts set forth above, and, had she been aware of said facts, she would not have acted as she did, that is, would not have utilized the product to help treat pain.

31. As a result of the concealment or suppression of the facts set forth above, Plaintiff sustained injuries and damages as hereinafter set forth.

32. That at all times herein mentioned, Defendants intentionally, willfully, and maliciously concealed or suppressed the facts set forth above from Plaintiff, with the intent to defraud Plaintiff as herein alleged.

33. At all times herein mentioned, neither Plaintiff nor her physicians were aware of the

facts set forth above, and, had she been aware of said facts, she would not have acted as she did, that is, that propoxyphene would not have been prescribed to Plaintiff.

34. As a result of the concealment or suppression of the facts set forth above, Plaintiff suffered injuries and damages as hereinafter set forth.

WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

V. RELIEF REQUESTED

Paragraphs 1-34 are herein incorporated by reference:

The plaintiff asks for judgments against the Defendants in an amount which will fairly compensate:

a. those who are eligible for compensation for economic and non-economic losses resulting from the death of Gaylene Johnson; and

b. the next of kin of Gaylene Johnson for the claims Gaylene Johnson could have brought against the defendants if she had survived.

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

1. For general damages in an amount within the jurisdiction of the District Court;
2. For hospital, medical and incidental expenses in an amount that is yet to be ascertained;
3. Pecuniary and economic losses in an amount that is yet to be ascertained;
4. For costs of suit herein;
5. Pre and post judgment interest; and
6. For such other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

Dated: July 13, 2007.

GOLDENBERG & JOHNSON, PLLC

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ACKNOWLEDGMENT REQUIRED BY
MINN. STAT. SEC. 549.211, SUBD. 2

The undersigned hereby acknowledges that, pursuant to Minn. Stat. Sec. 549.211, subd. 2, costs, disbursements and reasonable attorney and witness fees may be awarded to the opposing party or parties in this litigation if the Court should find the undersigned acted in bad faith, asserted a claim or defense that is frivolous and that is costly to the other party, asserted an unfounded position solely to delay the ordinary course of the proceedings or to harass, or committed a fraud upon the Court.

Dated: July 13, 2007.

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